



1642 / IFW

PATENT
Attorney Docket No. LEX-007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Gillies *et al.* CONF. NO.: 3473
SERIAL NO.: 09/621,268 GROUP NO.: 1642
FILING DATE: July 21, 2000 EXAMINER: Canella, K.A.
TITLE: Fc Fusion Proteins for Enhancing the Immunogenicity of Protein and Peptide Antigens

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Applicants believe no fee is required for entry and consideration of this paper. If a fee is required, please charge Deposit Account 20-0531.

Respectfully submitted,

Date: October 18, 2004
Reg. No. 48,645

Tel. No.: (617) 248-7697
Fax No.: (617) 248-7100

3130602_1



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TITLE: Fc Fusion Proteins for Enhancing the Immunogenicity of Protein and Peptide Antigens

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 18th day of October, 2004.


Susan Boucher

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith is/are:

1. Transmittal Form (1 page);
2. Fourth Supplemental IDS (2 pages);
3. Form PTO-1449 (2 pages);
4. Copies of cited references (A92-A108 and C236-C255); and a
5. Return receipt postcard.

TRANSMITTAL FORM

Application Serial Number	09/621,268
Filing Date	July 21, 2000
First Named Inventor	Gillies
Group Art Unit	1642
Examiner Name	Canella, K.A.
Attorney Docket No.	LEX-007
Patent No.	Not applicable
Issue Date	Not applicable

ENCLOSURES (check all that apply)

- | | | |
|---|---|---|
| <input type="checkbox"/> Fee Transmittal Form
<input type="checkbox"/> Check Attached
<input type="checkbox"/> Copy of Fee Transmittal Form

<input type="checkbox"/> Amendment/Response
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<input type="checkbox"/> After Final
<input type="checkbox"/> Affidavits/declaration(s)
<input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____]

<input type="checkbox"/> Petition for Extension of Time

<input checked="" type="checkbox"/> Fourth Supplemental Information Disclosure Statement
<input checked="" type="checkbox"/> Form PTO-1449
<input checked="" type="checkbox"/> Copies of Fourth Supp. IDS Citations (A92-A108; C236-C255)

<input type="checkbox"/> Certified Copy of Priority Document(s)

<input type="checkbox"/> Sequence Listing submission
<input type="checkbox"/> Paper Copy/CD
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<input type="checkbox"/> Statement verifying identity of above | <input type="checkbox"/> Copy of Notice to File Missing Parts of Application

<input type="checkbox"/> Formal Drawing(s)

<input type="checkbox"/> Request For Continued Examination (RCE) Transmittal

<input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)

<input type="checkbox"/> Terminal Disclaimer

<input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application

<input type="checkbox"/> Small Entity Statement

<input type="checkbox"/> CD(s) for large table or computer program

<input type="checkbox"/> Amendment After Allowance

<input type="checkbox"/> Request for Certificate of Correction
<input type="checkbox"/> Certificate of Correction (in duplicate) | <input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences

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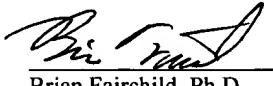
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<input type="checkbox"/> Additional Enclosure(s) (please identify below) |
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FORM PTO - 1449

FOURTH SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-007

APPLICANT(S): Gillies *et al.*

SERIAL NO.: 09/621,268

FILING DATE: July 21, 2000 GROUP: 1642

U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A92	5,601,819	2/11/97	Wong et al.			
	A93	5,891,680	4/6/99	Lieschke et al.			
	A94	5,994,104	11/30/99	Anderson et al.			
	A95	6,444,792	9/3/02	Gray et al.			
	A96	6,500,641	12/31/02	Chen et al.			
	A97	6,551,592	4/22/03	Lindhofer et al.			
	A98	6,646,113	11/11/03	Dreyfuss et al.			
	A99	2002/0037558	3/28/02	Lo et al.			
	A100	2002/0146388	10/10/02	Gillies			
	A101	2003/0139365	7/24/03	Lo et al.			
	A102	2003/0139575	7/24/03	Gillies			
	A103	2004/0013640	1/22/04	Zardi et al.			
	A104	2004/0033210	2/19/04	Gillies			
	A105	2004/0043457	3/4/04	Schumacher et al.			
	A106	2004/0053366	3/18/04	Lo et al.			
	A107	2004/0072299	4/15/04	Gillies et al.			
	A108	2004/0082039	4/29/04	Gillies et al.			
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)						
	C236	Chapman et al., (1994), "Mapping Effector Functions of a Monoclonal Antibody to GD3 by Characterization of a Mouse-Human Chimeric Antibody," <u>Cancer Immuno. Immunother.</u> , 39:198-204.					
	C237	Cruse et al., (eds.), (1995), <u>Illustrated Dictionary of Immunology</u> , p.158, CRC Press, NY.					
	C238	Dorai et al., (1991), "Aglycosylated Chimeric Mouse/Human IgG1 Antibody Retains Some Effector Function," <u>Hybridoma</u> , 10(2):211-217.					
	C239	Dorai et al., (1992), "Role of Inter-Heavy and Light Chain Disulfide Bonds in the Effector Functions of Human IgG1," <u>Molecular Immunology</u> , 29(12):1487-1491.					
	C240	Elliott et al., (1996), "Fine-Structure Epitope Mapping of Antierythropoietin Monoclonal Antibodies Reveals a Model of Recombinant Human Erythropoietin Structure," <u>Blood</u> , 87(7):2702-2713.					
	C241	Gillies et al., (1991), "Targeting Human Cytotoxic T Lymphocytes to Kill Heterologous Epidermal Growth Factor Receptor-Bearing Tumor Cells: Tumor-Infiltrating Lymphocyte/Hormone Receptor/Recombinant Antibody," <u>J. Immunology</u> , 146(3):1067-1071.					
EXAMINER				DATE CONSIDERED			

FORM PTO - 1449 FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTORNEY DOCKET NO.: LEX-007 APPLICANT(S): Gillies <i>et al.</i> SERIAL NO.: 09/621,268 FILING DATE: July 21, 2000 GROUP: 1642	
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)		
	C242	Handgretinger et al., (1995), "A Phase I Study of Human/Mouse Chimeric Anti-ganglioside GD2 Antibody ch14.18 in Patients with Neuroblastoma," <u>European J. Cancer</u> , 31A(2):261-267.	
	C243	Isenman et al., (1975), "The Structure and Function of Immunoglobulin Domains: II. The Importance of Interchain Disulfide Bonds and the Possible Role of Molecular Flexibility in the Interaction between Immunoglobulin G and Complement," <u>J. Immunology</u> , 114(6):1726-1729.	
	C244	Lo et al., (1992), "Expression and Secretion of an Assembled Tetrameric CH2-deleted Antibody in <i>E. Coli.</i> ," <u>Hum. Antibod. Hybridomas</u> , 3:123-128.	
	C245	Maecker et al., (1997), "DNA Vaccination with Cytokine Fusion Constructs Biases the Immune Response to Ovalbumin," <u>Vaccine</u> , 15(15):1687-1696.	
	C246	Mueller et al., (1990), "Enhancement of Antibody-Dependent Cytotoxicity With A Chimeric Anti-GD2 Antibody," <u>J. Immunology</u> , 144(4):1382-1386	
	C247	Mueller et al., (1990), "Serum Half-Life and Tumor Localization of a Chimeric Antibody Deleted of the CH2 Domain and Directed Against the Disialoganglioside GD2," <u>Proc. Natl. Acad. Sci. USA.</u> , 87:5702-5705.	
	C248	Naramura et al., (1993), "Therapeutic Potential of Chimeric and Murine Anti-(Epidermal Growth Factor Receptor) Antibodies in a Metastasis Model for Human Melanoma," <u>Cancer Immuno. Immunother.</u> , 37:343-349.	
	C249	Reisfeld et al., (1994), "Potential of Genetically Engineered Anti-Ganglioside GD2 Antibodies for Cancer Immunotherapy," <u>Prog. Brain Res.</u> , 101:201-212	
	C250	Saleh et al., (1992), "Phase I Trial of the Chimeric Anti-GD2 Monoclonal Antibody ch14.18 in Patients With Malignant Melanoma," <u>Hum. Antibod. Hybridomas</u> , 3:19-24.	
	C251	Wen et al., (1994), "Erythropoietin Structure-Function Relationships: Identification of Functionally Important Domains," <u>J. Biological Chemistry</u> , 269(36):22839-22846.	
	C252	Ghetie et al., (1997), "FcRn: the MHC class I-related receptor that is more than an IgG transporter," <u>Immunology Today</u> , 18(12):592-598.	
	C253	Junghans et al., (1996), "The protection receptor for IgG catabolism is the β_2 -microglobulin-containing neonatal intestinal transport receptor," <u>Proc. Natl. Acad. Sci. USA</u> , 93:5512-5516.	
	C254	Takai, (2002), "Roles of Fc Receptors in Autoimmunity," <u>Nat. Rev. Immunol.</u> , 2(8):580-592.	
	C255	Zhu et al., (2001), "MHC Class I-Related Neonatal Fc Receptor for IgG Is Functionally Expressed in Monocytes, Intestinal Macrophages, and Dendritic Cells," <u>J. Immunology</u> , 166:3266-3276.	
EXAMINER		DATE CONSIDERED	